

NOV 2 5 2005 B

PATENT IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(Case No. 05-530)

În re A	pplication of:)
Guitt Serial Filed:	tet et al. No.: 10/540,444 June 22, 2005)) Group Art Unit: Unknown) Examiner: Not Assigned)
For:	Scoring Estrogen and Progesterone Receptors Expression Based on Image Analysis)))

Commissioner for Patents P.O. Box 1450 Arlington, Virginia 22313-1450

TRANSMITTAL LETTER

Sir:

; · . · .

Fort

In regard to the above identified application:

- 1. We are transmitting herewith the attached:
 - a. Information Disclosure Statement
 - b. Statement of Relevancy of Foreign Language Reference
 - c. Copy of Cited Non-U.S. Patent References
 - d. Return Receipt Postcard
- 2. With respect to additional fees:
 - a. Attached is a check in the amount of \$_-0-
- 3. Please charge any additional fees or credit overpayment to Deposit Account No.13-2490. A duplicate copy of this sheet is enclosed.
- 4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of November, 2005.

Respectfully submitted,

By:

A. Blair Hughes Reg. No. 32,901

McDONNELL BOEHNEN, HULBERT & BERGHOFF LLP 300 SOUTH WACKER DRIVE CHICAGO, ILLINOIS 60606 TELEPHONE (312) 913-0001

100

A.





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 05-530)

In re A	application of:)	
Guit	tet et al.)	
)	Group Art Unit: Unknown
Serial	No.: 10/540,444)	
)	Examiner: Not Assigned
Filed:	June 22, 2005)	
)	
For:	Scoring Estrogen and Progesterone)	
	Receptors Expression Based on)	
	Image Analysis)	

Statement of Relevancy of a Foreign Language References

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The Mink et al. "Einstaz der computergestutzen Bilanalyse zur Erfassung des immunhistochemischen Rezeptorstatus beim Mammakarzinom" reference, which is cited in an Information Disclosure Statement by Applicant filed contemporaneously with this Statement, is being supplied in a language other than in English. The relevancy of the foreign language reference is identified in the European Search Report issued by the European Patent Office in a corresponding European Patent (a copy of which are hereto) which identifies the reference as an "A" reference with respect to claims 1-27 meaning it is a "document defining the general state of the art which is not considered to be of particular relevance".

Respectfully submitted,

McDONNELL BOEHNEN HULBERT &

BERGHOFF LLP

Dated: November 22, 2005 By:

A. Blair Hughes

Reg. No. 32,901

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 South Wacker Drive Chicago, Illinois 60606

NOV 2 5 2005

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

er the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 3

01	inpiete ii Kriowii	`
Application Number	10/540,444	
Filing Date	June 22, 2005	
First Named Inventor	Guittet	
Art Unit	Unknown	
Examiner Name	Not Assigned	-
Attorney Docket Number	05-530	

Complete if Known

			U. S. PATEN	T DOCUMENTS		
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		^{US-} 5,202,931	4-13-93	Bacus		
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
	<u> </u>	US-			0.36704 (074.5)	
		US-			- 154 M.St. 1-	
, popular con		US-			7. T. M. C.	
		US-				
	<u> </u>	ÚS-				
		US-				
	i ·	US-			- 1	
		US-				
V.		US-			1. September 1998	
·		US-				
E. 3.5		US-				
11		US-			or recevant	
				! 	A PART AND MAKE A PART AND A PART	

		FORE	IGN PATENT DOCU	MENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (if known)	MM-DD-YYYY	,,	Or Relevant Figures Appear	T ⁶
					. A 1 To A house and discussioning	
<u> </u>	ļ				to the improve pay plan	
<u></u>						
					, 44.1 Americ	
						•

Examiner	Date	
Signature	Considered	
T.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language. Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ute for form 1449/PTO				Complete if Known
Cubban			Application Number	10/540,444	
INF	ORMATION	DIS	CLOSURE	Filing Date	June 22, 2005
STA	ATEMENT B	BY A	PPLICANT	First Named Inventor	Guittet
	(Use as many she	note se r	occesand	Art Unit	Unknown
	(Ose as many sin	sera ag 1	iecessaiy)	Examiner Name	Not Assigned
Sheet	2	of	3	Attorney Docket Number	05-530

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Rothman et al. "Potential Use of Spectral Image Analysis for the Quantitative Evaluation of Estrogen Receptors in Breast Cancer", Histology and Histopathology, pp. 1051-57	
		Camp et al., "Automated Subcellular Localization and Quantification of Protein Expression in Tissue Microarrays", Nature Medicine, pp. 1323-27, Vol. 8, no. 11 (2002)	
		Schnorrenberg et al., "Computer-Aided Detection of Breast Cancer Nuclei", IEEE, pp. 128-140 (1997)	
· .		Roca et al., "Immunohistochemcial Correlation of Steroid Receptors and Disease-Free Interval in 206 Consectutive Cases of Breast Cancer:	
		Validation of Telequantification Based on Global Scene Segmentation", Analytical Cellular Pathology, pp. 151-163 (1995)	TO SECTION ASSESSMENT
		Sklarew, et al. "Comparison of Microscopic Imaging Strategies for Evaluating Immunocytochemical (PAP) Steriod Receptor Heterogeneity", Cytometry, pp. 207-220 (1991)	and the state of
 . ·		Mink et al., "Einsatz der computergestuzen bildanalyse zur erfassung des immunhistochemischen rezeptorstatus beim mammakarzinom	
		immunhistochemischen densitometrische rezeptroanalyse -IDRA", Geburtsh Frauenheilk, pp. 617-623 (1992)	
***		El-Badawy et al. "Immunohistochemcial Progesterone Receptor Assay", Amer. Journal of Anatomic Pathology, pp. 704-710 (1991)	
		True, "Quantitative Immunohistochemical Assay of Estrogen Receptors by Image Analysis", Laboratory Investigation, pp. 80A (1987)	

	8	
Examiner	Date	germen man
		· · · · · · · · · · · · · · · · · · ·
Signatura	l Conside	and '
Signature	Consider	rea

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
to a collection of information unless it contains a valid OMB control number.

	ite for form 1449/PTO		ct of 1995, no persons an	Complete if Known		
Cubonio	Substitute for form 1445/1 Fo		Application Number	10/540,444		
INF	ORMATION	DIS	CLOSURE	Filing Date	June 22, 2005	
STATEMENT BY APPLICANT				First Named Inventor	Guittet	
	(Use as many she	ate se r	ocaccan/l	Art Unit	Unknown	
(ooc as many sheets as necessary)				Examiner Name	Not Assigned	
Sheet	3	of	3	Attorney Docket Number	05-530	フ

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Lehr et al., "Quantitative Evaluation of HER-2/neu Status in Breast Cancer by Fluorescence in situ Hybridization and by Immunohistochemistry	
		with Image Analysis", American Journal of Clinical Pathology, pp. 814-822 (2001)	
		Esteban, et al. "Biologic Significance of Quantitative Estrogen Receptor Immunohistochemical Assay by Image Analysis in Breast Cancer",	
		American Journal of Clinical Pathology,, pp. 158-162 (1994)	hard Marketon (1, response of 1, res
		Cavaliere et al. "Computer-assisted Immunocytochemical Determination of Breast Cancer Steroid Receptors. Frozen Sections vs Paraffin Sections", The Breast, pp. 476-483 (2001)	en ben mustik in de e
		Tsapatsoulis et al., "An Image Analysis System for Automated Detectioon of Breast Cancer Nuclei", IEEE, pp. 512-515 (1997)	
		· · · · · · · · · · · · · · · · · · ·	minus i kaja dinavada i m
			A Section of the sect

Examiner	Date	$\overline{}$
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.